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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/801,157   | 03/07/2001  | Hans-Peter Josel     | RDID0089DUS         | 1582             |
| 757  | 7590        | 06/18/2007           | EXAMINER            |                  |
| BRINKS HOFER GILSON & LIONE<br>P.O. BOX 10395<br>CHICAGO, IL 60610 |             |                      | EPPERSON, JON D     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/801,157             | JOSEL ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jon D. Epperson        | 1639                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 March 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 33-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 33-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Application***

1. The Response filed March 23, 2007 is acknowledged.
  
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

### ***General Comments***

3. Applicants stated that a translation of the Yan reference had not been provided. However, the Examiner notes that a translation of said reference was provided with the 3/1/07 office action. If another copy is needed, please contact the Examiner.

### ***Status of the Claims***

4. Claims 33-39 were pending. Claims 33, 34, and 37 were amended. In addition, claim 4-40 was added. No claims were canceled. Therefore, claims 33-40 are examined on the merits.

### **Withdrawn Objections/Rejections**

5. The objection over claim 37 is withdrawn in view of Applicants' amendments thereto. The rejection under 35 U.S.C. § 112, second paragraph denoted "A" is withdrawn in view of Applicants' amendments to the claims. All other rejections are maintained and the arguments are addressed below.

### **Outstanding Objections and/or Rejections**

***Claim Rejections - 35 USC § 103***

6. Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bredehorst et al. (Bredehorst, R.; Wemhoff, G. A.; Kusterbeck, A. W.; Charles, P. T.; Thompson, R. B.; Ligler, F. S.; Vogel, C.-V. "Novel Trifunctional Carrier Molecule for the Fluorescent Labeling of Haptens" *Analytical Biochemistry* **1991**, 192, 272-279) and Brinkley (Brinkley, M. "A brief Survey of Methods for Preparing Protein Conjugates with Dyes, Haptens and Cross-linking Reagents" *Bioconjugate Chem.* **1992**, 3, 2-13) and Yang (Yan, S.; Niu, J. "Solid phase synthesis of the A-chain of insulin and its recombination with the B-chain to crystalline insulin" *Shengwu Huazue Yu Shengwu Wuli Xuebao* **1992**, 24(5), 497-502).

For **claim 33**, Bredehorst et al. (see entire document) teach a method for the synthesis of novel trifunctional carrier for the fluorescence labeling of haptens (e.g., see abstract), which reads on the claimed invention. For example, Bredehorst et al. teach the use of a linear peptide carrier (e.g., see Bredehorst, page 275, figure 1 showing "insulin A-chain" carrier). In this scenario, the first two amino acids (or, alternatively, any other length less than 19 e.g., the first three, first four, etc.) of the insulin chain represent the linear carrier. That is, at least two amino acids have been "linked" together to form a linear chain. Consequently, any of the remaining amino acids (i.e., 21 – first two, 21 – first three, 21 – first four, etc. wherein "21" is the "total" length of the insulin A-chain shown if figure 1 on page 275) represent "additional" amino acids to which the DNP hapten molecule and two remaining DNP molecules are covalently attached through either the terminal Gly or hydrazine linkers respectively (e.g., see page 275, figure 1 showing attachment of 1 DNP and 2 Fl groups bound to the Glu residues). For example,

in one alternative interpretation one DNP hapten and one Fluorescein group are attached to the carrier (i.e., Asn→Gln) via a Gly-Ile-Val-Glu “additional” tetrapeptide (i.e., the carrier is viewed as being the insulin A-chain without the Gly-Ile-Val-Glu tetrapeptide, instead of the insulin A-chain in its entirety). Thus, in this scenario, four “additional” amino acids have been “introduced” to the Asn→Gln peptide. Please note that Applicants’ use of “comprising” language does not preclude the addition of additional groups to the linear carrier. Furthermore, the claims do not require that the hapten/luminescent groups be bound to the amino acid side chains. The claims merely require that these groups bind to “amino groups, thiol groups, and a combination thereof” (e.g., see claim 33). Thus, the examiner has interpreted these claims as not excluding the use of linker molecules like hydrazine as long as “additional” amino acids have been added to the carrier and the hapten/luminescent groups are covalently attached (through the linker) to the linear carrier. Bredehorst et al. also disclose defining reproducible distances between the hapten and DNP groups (e.g., see figure 1 wherein three fluorescein molecules are disclosed; see also page 273, column 1, paragraph 1, “The sites for fluorophores attachment are 4, 17, and 21 amino acids away from the hapten attachment site”; see also page 277, column 2, paragraph 1, The backbone of the carrier is the A-chain of insulin which provides several essential features, including … (c) sufficient length between the label attachment sites to prevent self-quenching of the fluorophores, (d) sufficient length between the hapten and the label attachment sites to limit both interference by the fluorophores with antibody binding to the hapten and quenching of the fluorophores due to interaction with the hapten”). In addition,

Bredehorst et al. disclose that the conjugate comprising a minimum of 5 and a maximum of 100 amino acids (e.g., see figure 1, DNP-Ins-Fl wherein 21 amino acids are disclosed). Finally, Bredehorst et al. disclose the use of “amino” groups for binding the haptens (e.g., the N-terminus) and fluorescein molecules (e.g., via a hydrazine linker) (e.g., see Bredehorst et al., figure 1; see also Methods section, especially page 273, column 1, Synthesis of DNP-Ins-FL section).

For **claim 35**, Bredehorst et al. teach the use of an N-terminal primary amine to link the hapten to the carrier (e.g., see Bredehorst et al., figure 1).

The prior art teachings of Bredehorst et al. differ from the claimed invention as follows:

For **claim 33**, Bredehorst et al. fail to teach the use of solid-phase synthesis (see Bredehorst et al., page 273, column 1, last paragraph wherein Bredehorst et al. purchased the insulin carrier from Sigma and thus the reference is silent as to whether or not the insulin was produced via solid-phase synthesis). In addition, Bredehorst et al. fail to teach the use of luminescent metal chelates as marker molecules. Bredehorst et al. only teach the use of fluorescein markers instead (e.g., see Bredehorst et al., figure 1).

For **claim 34, 36, 37 and 40**, Bredehorst et al. do not teach the use of “protecting groups” in conjunction with the reactive side groups.

For **claims 38-39**, Bredehorst et al. do not teach the use of the haptens listed therein (e.g., see claims 38-39). Bredehorst et al. only teach the use of 2,4-dinitrophenol (e.g., see abstract).

However, the combined references of Brinkley, Yang and Massey et al. teach the

following limitations that are deficient in Bredehorst et al.:

For **claim 33**, the combined references of Brinkley, Yang and Massey et al. (see entire documents) teach the use of solid-phase synthesis to make peptides like the insulin carrier disclosed by Bredehorst et al. (e.g., see Yang et al., abstract wherein insulin A-chain was produced using solid-phase synthesis). In addition, the combined references of Brinkley, Yang and Massey et al teach the use of metal chelates for labeling haptens (e.g., see Massey et al., abstract, see also claim 11, “A method according to claim 1, wherein the reagent comprises an electrochemiluminescent chemical moiety conjugated to an ... hapten ... or biotin”; see also claims 15-20 wherein bipyridine chelators are disclosed).

In the alternative that Bredehorst et al. additionally fail to teach the use of 1-10 additional amino acids as “linker” molecules for the attachment of metal chelates or, alternatively, the hapten molecule (which is not the case, see above). For the sake of argument, the Examiner notes that the combined references of Brinkley, Yang and Massey et al. also teach this limitation (e.g., see Brinkley, section II.A. wherein the use of amino acids linker molecules with reactive “amino groups” such as lysine for the attachment of haptens and fluorophores to a conjugate (e.g., Brinkley, section II.A.).

For **claims 34, 36, 37 and 40**, the combined references of Brinkley, Yang and Massey et al. (see entire documents) teach the use of a wide variety of protecting groups (e.g., see Brinkley, page 2, column 2, paragraph 1, “in these molecules, the N-terminal amino group is N-acylated [i.e., protected]”; see also Yang, abstract, disclosing “tert-Bu” group for side chain protection and TFA for “selective” side chain removal).

For **claim 35**, the combined references of Brinkley, Yang and Massey et al. (see entire documents) also teach the use of primary amines including the  $\varepsilon$ -amine of lysine (e.g., see Brinkley, page 2, column 1, last paragraph).

For **claims 38-39**, the combined references of Brinkley, Yang and Massey et al. teach the use of haptens molecules like digoxin and theophyllin (e.g., see figures 6 and 7; see also Examples 32-34).

It would have been *prima facie* obvious to one skilled in the art at the time the invention to synthesize the peptide carrier molecule as disclosed by Bredehorst et al. on a solid-support as disclosed by Yang because Yang developed a solid-phase method for this exact purpose i.e., they developed a solid-phase method for the synthesis of the insulin A-chain (e.g., see Yang, abstract). Furthermore, a person of skill in the art would have been motivated to use solid-phase synthesis to obtain high yields of the purified insulin product using the facile washing procedures associated with the solid-phase process. Finally, a person of skill in the art would reasonably have expected to be successful because Yang explicitly state that they can produce the insulin A-chain on a solid-support using an Fmoc protection strategy (e.g., see Yang et al., abstract) and Bredehorst et al. teach how this insulin chain can be further derivatized once it is produced.

Furthermore, it would have been *prima facie* obvious to substitute the metal chelates (e.g., see claims 15-20) disclosed by Massey et al. for the fluorescein molecules disclosed by Bredehorst et al. because Massey et al. explicitly state that these metal chelates can be used to label haptens, which would encompass the 2,4-dinitrophenol

(DNP) hapten disclosed by Bredehorst et al. (e.g., see claim 11, “A method according to claim 1, wherein the reagent comprises an electrochemiluminescent chemical moiety conjugated to an ... hapten”). Furthermore, a person of skill in the art would have been motivated to use such metal chelates because Massey et al. explicitly states that their metal chelates are useful for immunoassays (e.g., see figures 1, 6 and 7; see also Summary of Invention; see also paragraph bridging pages 25-26), which would encompass the immunoassays disclosed by Bredehorst et al. (e.g., see Bredehorst et al., page 272, column 2, last paragraph). In addition, Massey et al. state that their metal chelates are “highly diagnostic of the presence of a particular label, sensitive, non-hazardous, inexpensive, and can be used in a wide variety of applications” (e.g., see Massey et al., page 5, paragraph 1; see also Examples 36 and 37). Finally, a person of skill in the art would have reasonably expected to be successful because Massey et al. state that their metal chelates “can be used in a wide variety of applications” (e.g., see Massey et al., page 5, paragraph 1) wherein the labeling of haptens represents a “preferred embodiment” (e.g., see Massey et al., claim 11; see also figures 1, 6 and 7; see also Examples; see also page 7). Massey et al. also state, “Extensive work has been reported on methods for detecting Ru(2,2'-bipyridine)<sub>3</sub><sup>2+</sup> using photoluminescent, chemiluminescent, and electrochemiluminescent means”, which shows that the art is not new and unpredictable (e.g., see Massey et al., page 7, last paragraph; see also page 32, lines 26-29 wherein Massey explicitly state that said metal chelates can be conjugated to haptens, “In one embodiment of the invention the reagent is a electrochemiluminescent chemical moiety conjugated to an ... hapten”).

Finally, it would have been *prima facie* obvious at the time the invention was made to use amino acid linkers, such as lysine, to attach the metal chelating groups disclosed by Massey et al. to the carrier peptide as disclosed by Bredehorst et al. because the method of attachment represents a mere design choice that was well known in the art (e.g., see Brinkley, entire document, reviewing various methods that were “standard” in the art for attaching haptens and/or labels to a carrier; see especially section II.A. wherein the use of lysine “handles” are disclosed). Furthermore, Brinkley explicitly state that amine-probes like lysine can be used to attach haptens like the DNP disclosed by Bredehorst et al. (e.g., see Brinkley, page 10, column 1, paragraph 2, “The following general procedure is ... adaptable to amine-reactive ... hapten”). A person of skill in the art would have been motivated to use lysine as linker for the attachment of the haptens and/or metal chelates because said lysine can be easily incorporated into a peptide and/or protein through synthesis and/or genetic manipulation (e.g., Brinkley, page 2, column 1, last full paragraph) and are “... reasonably good nucleophiles ... and therefore react easily and cleanly with a variety of reagents to form stable bonds” (e.g., see Brinkley, page 2, last paragraph). Finally, a person of skill in the art would have reasonably expected to be successful because Brinkley state that the  $\epsilon$ -amine of lysine is “one of the most common” reactive groups employed to link haptens and/or marker molecules to a protein conjugate (e.g., see Brinkley, page 2, last paragraph). In addition, Bredehorst et al. explicitly show that a hapten like 2,4-dintrophenol (DNP) can be linked to a marker molecule using lysine (e.g., see figure 1, compound DNP-Lys-Fl; see also page 278, column 1, first full paragraph, “In principle, labeling of a hapten with multiple

fluorophores is fairly simple. Polyamines such as polylysine ... are suitable").

***Response***

7. Applicant's arguments directed to the above 35 U.S.C. § 103(a) rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argued, "The rejection of claims 33-39 under 35 USC § 103 is respectfully traversed in view of the clarifying amendments to independent claims 33 and 34 ... Applicants respectfully submit that the claimed invention has not been properly understood. The principle misunderstanding appears to be that the claimed invention provides a mechanism for introducing amino acids carrying specific moieties ... during the synthesis of the carrier-not after the carrier has already been assembled ... Independent claims 33 and 34 have been rewritten to emphasize that the introduction of the moieties occurs during synthesis of the carrier. By contrast to the claimed invention, the references cited in the Office Action all relate to the modification of an existing carrier ... [thus, the prior art does not teach] first introducing amino acids comprising protected reactive side groups during synthesis of the peptide." (e.g., see 12/1/06 response, pages 6 and 7).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (e.g., "introducing amino acids carrying specific moieties "during" the synthesis of the carrier") are not recited in

the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, Applicants' claims are still broad enough to read on a process that introduces the modified amino acids "after" the synthesis (i.e., it reads on both processes wherein the modified amino acid is introduced "during" OR "after" the synthesis). For example, claim 33 does not read, "forming a linear carrier on a solid phase by linking amino acids wherein said 1-10 amino acids covalently bound to hapten molecules ... are introduced into the carrier" that might otherwise require the use of modified amino acids in the formation of the linear chain. As independent claims 33 and 34 are currently written "additional" amino acids can still be used to introduce the hapten/chelate molecules into the carrier (i.e., since the word "said" is missing). Consequently, Applicants' arguments are moot.

### New Rejections

#### *Claims Rejections - 35 U.S.C. 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 33-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

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A. Independent claim 33 and 34 were amended in the 12/1/06 response.

However, the specification does not support the full scope of the claimed amendments.

For example, both claims 33 and 34 have been amended to read on a process where a hapten/luminescent metal chealate modified amino acid is introduced into a carrier both “during” and “after” the synthesis of said carrier. Thus, to the extent that the claimed scope has been expanded from processes that introduce these amino acids “after” said synthesis to processes that introduce these amino acids “during” said synthesis, such increased breadth represents new matter. This can most clearly be seen for species like “steroids” (e.g., see claim 38 wherein several steroids are disclosed) and other sensitive compounds like sensitive fluorescent dyes wherein Applicants have already admitted that these compounds cannot be introduced “during” the synthesis but, rather, can only be introduced “after” said synthesis (e.g., see specification, page 13, last full paragraph, “The haptens and marker or solid phase binding groups are preferably introduced ... by using monomer derivatives during the solid phase synthesis ... However, in the case of sensitive fluorescent dyes or labels or other haptens such as steroids this procedure is unsuited since these substances can be destroyed under the conditions of the solid phase syntheses.”). If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02.

9. Claims 33-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods that introduce hapten/luminescent metal chelates-modified

amino acids that are not “sensitive” to the conditions of solid-phase synthesis, does not reasonably provide enablement for sensitive compounds like steroids, fluorescent dyes, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. Some of these factors may include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are drawn to a broad genus of methods for producing conjugates using a wide array of hapten molecules and/or luminescent metal chelates wherein said haptens/chelates are introduced into a carrier molecules either during or after synthesis. Given the wide array of structures that could fall within the scope of a hapten molecule, the nature of the invention cannot be fully determined because the invention has not been defined with particularity.

(3 and 5) The state of the prior art and the level of predictability in the art: The level of predictability with regard to the “sensitive” compounds is low or absent. In fact, Applicants admit that such compounds will not work using methods that employ hapten/chelate-modified amino acids during the synthesis (e.g., see specification, page 13, last full paragraph, “The haptens and marker or solid phase binding groups are preferably introduced ... by using monomer derivatives during the solid phase synthesis ... However, in the case of sensitive fluorescent dyes or labels or other haptens such as steroids this procedure is unsuited since these substances can be destroyed under the conditions of the solid phase syntheses.””).

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have not provided any examples of “sensitive” compounds for use “during” the synthesis of the carrier. Although Applicants expressly claim these compounds (e.g., see claim 38 wherein various steroids are disclosed), the specification, as noted above, expressly states that these compounds will not work.

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, the Examiner contends that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as

broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 \* n.23 (Fed. Cir. 1999).

Please note that this is a “scope of enablement” rejection. Thus, while some embodiments are enabled (see art above), the vast majority of embodiments are not (e.g., see discussion with regard to “sensitive” compounds above.

### ***Conclusion***

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.  
June 10, 2007

JON EPPERSON  
PRIMARY EXAMINER

